IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, Plaintiff, v. WALMART INC. AND WAL-MART STORES EAST, LP, Defendant.	C.A. No. 20-1744-CFC

REPLY BRIEF IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

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I. THE COMPLAINT DOES NOT PLAUSIBLY ALLEGE THAT ANY WALMART EMPLOYEE KNOWINGLY FILLED AN INVALID PRESCRIPTION (COUNT I).

The Government admits that § 1306.04(a) requires it to show (i) an "invalid prescription" that (ii) was "knowingly" filled. D.I. 42 ("Opp.") 9. The Complaint, however, does not identify a *single instance* in which anyone at Walmart filled an invalid prescription despite actually knowing it was invalid.

A. Instead of Alleging Knowledge, the Government Objects to Walmart's Corporate Protocols for Information-Sharing.

The Complaint's lead § 1306.04(a) theory is that Walmart pharmacists filled prescriptions by doctors about whom *other* Walmart employees reported potentially relevant information. That is an effort to retroactively impose novel information-sharing duties, not to establish the scienter required under the existing regulation.

At the outset, the Government tries to evade review by claiming that Walmart cannot move to dismiss "*parts* of claims." Opp. 13. But the Government relies on inapposite out-of-circuit dicta. *See IBM Corp. v. Priceline Grp.*, No. 15-cv-0137, 2017 WL 1349175, at *6-7 (D. Del. Apr. 10, 2017) (rejecting this dicta). Courts in this circuit regularly narrow claims to reject non-viable theories. *E.g.*, *id.*; *OpenGate Cap. Grp. LLC v. Thermo Fisher Sci. Inc.*, No. 13-cv-1475, 2014 WL 3367675, at *15 (D. Del. July 8, 2014); *Doe v. Trs. of Univ. of Pa.*, 270 F. Supp. 3d 799, 813-15, 822, 826, 831 (E.D. Pa. 2017). The alternative is lengthy, wasteful discovery in support of legally hopeless theories.

On the merits, the Government disclaims collective knowledge. Opp. 9. The parties thus appear to agree that Walmart is liable only if a particular employee with a "role" in dispensing a prescription (Opp. 14) knew it was invalid.

The Government argues, though, that even where the dispensing pharmacist was "unwitting," Walmart is liable based on its "compliance managers' knowledge." *Id*. But each of the Government's four theories for locating scienter in Walmart's compliance unit legally fails.

To start, contrary to the Government's recharacterizations (Opp. 5-6, 9), the Complaint includes no allegation that any compliance manager knew any particular prescription was invalid, let alone played a role in filling it. It alleges that the unit would "field[] questions" and develop "internal guidance" (Compl. ¶¶ 123-24) and, in both respects, always reminded pharmacists to use "professional judgment" as to each individual prescription (*e.g.*, *id.* ¶¶ 231, 237, 384; *see also id.* ¶¶ 125-34). At most, the Complaint alleges that the compliance employees had *access* to reports by pharmacists that *might have been relevant* to the validity of prescriptions presented to *other* pharmacists—not that the compliance team knew of those prescriptions or ever formed any belief on their validity. That distinguishes *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, which "required the jury to find at least one Westinghouse employee" who "alone" knew "all the facts." 352 F.3d 908, 918 n.9 (4th Cir. 2003). The Government identifies no such employee here.

To bridge the gap, the Government argues that, based on Walmart's allegedly inadequate systems, it was "substantially certain" some invalid prescriptions would be filled, allowing an inference that the compliance unit so *intended*. Opp. 16-17. But "even a very high risk" is "not enough to show substantial certainty." *Eddy v. Virgin Islands Water & Power Auth.*, 369 F.3d 227, 232 (3d Cir. 2004). Rather, one must expect a "specific" harm at "a particular time and place," *Dobb's Law of Torts* § 29 (2d ed. 2020), not just risk "at some undefined time and place," *Restatement (3d) of Torts: Phys. & Emot. Harm* § 1 cmt. e (2010). Yet the Complaint's objections to Walmart's policies show only the latter; it never identifies any employee who knew with "virtual certainty," *Eddy*, 369 F.3d at 232, of any *particularized* violation.

Nor does the Complaint allege a basis for willful blindness, which is when someone "take[s] deliberate actions to avoid learning" of a fact despite subjectively believing "there is a high probability that [the] fact exists." *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011). There is no allegation that compliance managers did anything to "shield[] themselves," *id.* at 766, from facts. And while the Government claims they "shielded pharmacists" from potentially relevant data (Opp.18), the Complaint admits the compliance unit shared that very refusal-to-fill data on request; discussed creating a system for broader circulation; and by 2015 rolled out a searchable platform (Compl. ¶¶ 156-57, 160). Too little, too late, says the Government (*id.* ¶¶ 161-64)—but that is a far cry from *willful blindness*.

Finally, the Government observes that knowledge can be "imputed" *if* there is a "regulatory duty" to "share information." Opp. 17. Such a duty is "essential" for corporate liability. *Restatement (Second) of Agency* § 275 cmt. c (1958). But the Government cites no rule imposing such a duty—as it never promulgated one.[1] And there's the rub. The Government is trying to compensate for its failure on that front by imputing the compliance team's data to pharmacists. That is overreach.

B. The Complaint's Categorical Allegations Do Not Support a Plausible Inference of Any Knowing Misconduct.

More generally, none of the types of prescriptions identified by the Complaint are allegedly *per se* invalid. As the Government's putative amicus notes, a "totality of the circumstances" inquiry applies. D.I. 44-1 at 8. Even doctors whose practices draw concern can write legitimate prescriptions if they are state-licensed and DEA-registered. Prescriptions with "red flags" may be more *likely* to be invalid, but are not *necessarily* so. And pharmacists can reach different judgments about the same prescription. D.I. 27 ("MTD") 15-17. The Government does not deny any of this, and its use of qualifiers implicitly admits it. *E.g.*, Opp. 4 (doctors "routinely" wrote invalid prescriptions); Opp. 6 (red-flag prescriptions "presumptively" invalid).

[1] The Government instead cites an unpublished trial-court order, and even it held only that a pharmacy "cannot be deliberately ignorant or willfully blind," *In re Nat'l Prescription Opiate Litig.*, No. 17-MD-2804, 2020 WL 5642173, at *2 (N.D. Ohio Sept. 22, 2020), not that pharmacy chains must employ the information-sharing protocols Walmart allegedly lacked. As for Walmart's 2011 agreement with DEA, it only required sharing refusal-to-fill reports *with DEA* (Compl. ¶ 139).

Given those admissions, no inference of wrongdoing arises from the fact that Walmart filled *some* prescriptions in these categories while refusing others; that is exactly what one would expect. MTD 15. Yet that is all the Complaint alleges. It does not allege *how often* those prescriptions were filled versus refused, or that the ratio was unusual. And while it provides raw numbers for prescriptions filled, those figures are in line with Walmart's size. *Id.* Without contextualizing allegations, the mere fact that some prescriptions in certain categories were filled cannot support a "reasonable inference," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), that Walmart *knowingly* filled invalid prescriptions. Otherwise the Government could pursue civil and criminal penalties against *any* pharmacy that filled *any* "red-flag" prescription.

The Government tries to seek refuge in pleading standards, but a complaint cannot proceed if its allegations are "merely consistent with" liability. *Id.*; *see also George v. Rehiel*, 738 F.3d 562, 586 (3d Cir. 2013). Particularly when the Complaint makes clear, through otherwise-detailed allegations, that the Government "had ready access to [Walmart] documents and employees" over the course of a long investigation, it is proper to expect a stronger "factual basis" for its claims. *EEOC v. Port Auth. of N.Y. & N.J.*, 768 F.3d 247, 258 (2d Cir. 2014). In this context, simply hoping "discovery will reveal evidence" (Opp. 9) rings hollow.

The Government then insists the Complaint alleges "Walmart pharmacists knowingly filled invalid prescriptions." *Id.* Actually, it does not. Every cited

example (Opp. 10-11) shows the opposite: The pharmacists took their professional responsibilities seriously and refused to fill prescriptions they believed to be invalid. One pharmacist announced he "might start to refuse to fill prescriptions" from a certain clinic; a compliance manager encouraged him to "exercise [his] independent judgment." Compl. ¶¶ 216-17. When pharmacists raised concerns about another doctor, they were advised to use their "professional judgment"; the Complaint does not say they filled further prescriptions. *Id.* ¶¶ 235-37. One pharmacist told DEA, "in retrospect," she "would not have filled" certain prescriptions (*id.* ¶ 321), but that implies she did *not* know they were invalid *at the time*. Other cited paragraphs give examples of prescriptions that were filled, but do not allege invalidity or *anything* about the pharmacist's knowledge. *E.g.*, *id.* ¶¶ 297, 367, 373, 412, 434.

Despite the Government's broad-brush briefing, the Complaint is careful *not* to allege any specific pharmacist filled any specific prescription she "recognized ... as invalid." Opp. 12. It sometimes says pharmacists "would have known" (Compl. ¶¶ 109, 357, 374, 383), but that is not *actual* knowledge, *see United States v. Khorozian*, 333 F.3d 498, 508 (3d Cir. 2003). That careful pleading is no accident. It reflects that the Government is not serious about proving § 1306.04(a)'s elements case-by-case. It wants to take shortcuts by condemning categories of prescriptions *in toto*. That conflicts with the CSA and the nature of medical and pharmacy practice. It also fails to satisfy the Government's burden, even on the pleadings.

II. THE GOVERNMENT CANNOT RECOVER CIVIL PENALTIES FOR EVERY ALLEGED DEVIATION FROM PROFESSIONAL STANDARDS (COUNT II).

In defending its duplicative Count II, the Government misunderstands both the substance of § 1306.06 and its relationship to the CSA's enforcement scheme.

A. The Government Offers No Coherent Explanation for How a Violation of § 1306.06 Triggers a Statutory Civil Penalty.

The Government admits that, to obtain civil penalties or an injunction, it must show "a violation of § 829." Opp. 23. With certain exceptions, § 829(a) states that "no [Schedule II] controlled substance ... may be dispensed without the written prescription of a practitioner." Yet the Government insists it need not show any "dispensing 'without a prescription'"—only departure from what it considers "the course of professional practice." Opp. 23. That position is legally baseless.

To explain how violating § 1306.06 involves violating § 829, the Government offers a convoluted account operating through a series of implicit cross-references and ultimately "incorporating" all of "Part 1306" of Title 21 of the Code of Federal Regulations. Opp. 23-25. This tortuous chain is severed by repeated non-sequiturs. Meanwhile, the statute is straightforward: Unless a pharmacist dispenses "without" a "prescription," he has not violated § 829. Not every professional misstep equals dispensing without a valid prescription; not every *regulatory* miscue amounts to a *statutory* offense. That is why DEA specified in § 1306.04(a), but nowhere else in its rules, that violations "shall be subject to the penalties provided" by the CSA.

None of the cases the Government cites remotely holds otherwise. Indeed, the Government does not identify *any case* that has ever imposed civil monetary penalties under § 1306.06. That silence is especially deafening because, on the Government's theory, that rule would offer the *easiest* path to relief.

With no textual or judicial support, the Government is left to complain that Walmart's interpretation is "absurd" since it would allow only the "draconian" remedy of deregistration for a pharmacy or "*criminal* prosecution" for a pharmacist. Opp. 27-28. That ignores that "the CSA presume[s] and rel[ies] upon a functioning ... profession regulated under the States' police powers." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). State regulators can penalize professional foot-faults. DEA can impose penalties if pharmacists knowingly fill invalid prescriptions, and can use revocation threats to ensure that registrants terminate bad pharmacists (like one who leaves drugs "unattended on a counter," in Defendants' fanciful example (Opp. 26)).

What would be "absurd" is if, after adding scienter to § 1306.04(a) to protect pharmacists (MTD 2), DEA swallowed that protection away by imposing equally severe penalties for unintentional, isolated deviations from professional standards. The Government suggests "Congress chose" strict liability (Opp. 27), but *United States v. Green Drugs* involved "recordkeeping requirements," 905 F.2d 694, 696-97 (3d Cir. 1990), not § 1306.06, and Congress later imposed a negligence standard even for those ministerial failures, Pub. L. No. 105-277, 112 Stat. 2681 (1998).

The Government also denies that its construction of § 1306.06 would swallow § 1306.04(a) (Opp. 21-22), but it is impossible to conceive of a § 1306.04(a) violation that would not also violate § 1306.06 on the Government's view, as no professional norm is more basic than *not knowingly filling invalid prescriptions*. Perplexingly, the Government also suggests § 1306.06 addresses "pharmacists" while § 1306.04(a) addresses "prescribers," and so neither is superfluous. Opp. 21. But Count I in this action is literally a claim *against pharmacists* under § 1306.04(a). Walmart's interpretation makes sense of the regulatory scheme; the Government's badly muddles it.

B. The Government's Definition of "Usual Course" Is Indefensible.

The Government (but tellingly, not its putative amicus) claims a pharmacist leaves the "usual course" anytime he transgresses "generally accepted" professional norms. Opp. 20. That conflates § 1306.06 with malpractice or negligence.

Starting with precedent, courts agree that professionals do *not* leave the usual course of practice by committing mere "malpractice." *United States v. Feingold*, 454 F.3d 1001, 1009 (9th Cir. 2006); *see also, e.g.*, *United States v. Volkman*, 797 F.3d 377, 388 (6th Cir. 2015) (proof of "negligen[ce]" is insufficient); *United States v. McIver*, 470 F.3d 550, 560 (4th Cir. 2006) ("Malpractice or negligence" differs from acting "outside the bounds of … professional medical practice."); *United States v. Zielke*, No. 17-cr-295, 2021 WL 1163868, at *6-7 (W.D. Pa. Mar. 26, 2021).

Those decisions reflect ordinary English. An attorney does not depart from the "usual course" of lawyering if he negligently misses a case in his research, and a doctor does not leave the "usual course" of medicine if she forgets to record a fact on a patient's chart. The "usual course" question is whether the professional has stopped acting as a professional "*at all*," not whether she is a "*bad*" one. *Feingold*, 454 F.3d at 1007, 1011. That is a meaningfully higher legal standard.

The cases that the Government cites illustrate that standard. In *United States v. Ludwikowski*, the pharmacist "filled narcotics prescriptions without verification" for cash, helped patients "fix the errors" on "forged" prescriptions, and gave opioids to an addict "six days a week" based on prescriptions bearing "different names." 944 F.3d 123, 137 (3d Cir. 2019). In *United States v. Shaker*, the doctor developed a sexual relationship with a patient and provided her with pain medication for years despite another doctor's advice that the patient did not need any. 827 F. App'x 204, 207-08 (3d Cir. 2020). In *United States v. Ruan*, the defendants ran a pain clinic and a next-door pharmacy, and prescribed enormous quantities of opioid products that were manufactured by companies in which they owned stock, often "without seeing patients, obtaining informed consent, or keeping accurate records." 966 F.3d 1101, 1124-26 (11th Cir. 2020) (cleaned up). These fact patterns exemplify what it means to act outside the usual course of professional practice; these are not just errors, or even repeated poor performance, but wholesale rejection of the professional's role.

The Government has no answer to these cases or reasoning, so it attacks straw-men. It first claims that Walmart rejects the relevance of professional standards and notes that "[c]ourts routinely accept" expert testimony on those norms. Opp. 20, 22. The former is not Walmart's position and the latter is unsurprising. "[I]t is the *extent* and *severity* of departures from … professional norms" that bear on whether a professional has left the usual course. *McIver*, 470 F.3d at 561 (emphasis added). Walmart's position is not that professional standards are legally irrelevant, but that "merely departing from" them does not violate § 1306.06.

The Government next says § 1306.06 prohibits more than just "'drug pusher' behavior." Opp. 20-21. That too is undisputed. Acting "as a large-scale 'pusher'" is one obvious instance in which physicians and pharmacists leave the usual course. *United States v. Moore*, 423 U.S. 122, 143 (1975). But they do so *whenever* they so grossly depart from professional roles that their authority over controlled substances is "being used not for treatment of a patient," but for other, illegitimate ends. *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994).

The Government never comes close to alleging that Walmart pharmacists, who were trained to reject invalid prescriptions and routinely did so (MTD 17 n.2), did anything rising to that level. Tellingly, it does *not* argue in the alternative that the Complaint states a claim even if Walmart's interpretation of the rule is correct. *Cf.* Opp. 30 n.6 (making that alternative argument for Count III).

III. THE GOVERNMENT IS WRONG ABOUT BOTH THE DUTY TO REPORT SUSPICIOUS ORDERS AND THE AVAILABLE PENALTIES (COUNT III).

In arguing that Walmart violated a regulatory duty to report suspicious orders, the Government again misconstrues the duty's scope and its enforcement regime.

A. Until Congress Amended the CSA, Only Administrative Penalties Were Available for Failing To Report Suspicious Orders.

The Government admits it can recover civil penalties only if suspicious-order reports were "required under this subchapter." 21 U.S.C. § 842(a)(5). It also admits such reporting was required only by *regulation* during the relevant period. 21 C.F.R. § 1301.74(b). But the Government insists—with no supporting cases—that reports mandated by regulation are "required under" the CSA. Opp. 31-32. That is wrong.

Of course, "under" alone is ambiguous; "context" is required. Opp. 32. But the context here parallels that in *Kucana v. Holder*, 558 U.S. 233, 237 (2010), which adopted Walmart's reading and which the Government fails to distinguish.

First, reading "under" to include regulations would mean the 2018 SUPPORT Act's creation of a *statutory* reporting duty, 21 U.S.C. § 832(a), had *no effect*—something the Government never denies. MTD 30-31. Yet "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Stone v. INS*, 514 U.S. 386, 397 (1995). Amendments therefore do properly bear on how original text should be construed. *E.g.*, *Tex. Dep't of Hous. & Cmty. Affs. v. Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 535-36 (2015).

This is not impermissible resort to "subsequent legislative history" (Opp. 36);[2] it is adherence to the "fundamental canon" that terms "be read in their context" in "the overall statutory scheme," *Sturgeon v. Frost*, 577 U.S. 424, 438 (2016), and to avoid "render[ing] superfluous another part of the same statutory scheme," *City of Chicago v. Fulton*, 141 S. Ct. 585, 591 (2021). Unlike in *Almendarez-Torres v. United States*, the amendments here "depend for their effectiveness" on reading "the earlier enacted provisions" as Walmart urges. 523 U.S. 224, 237 (1998).

Second, Congress mentioned regulations in the CSA *expressly* when it wanted to. MTD 29; *Kucana*, 558 U.S. at 248. The Government responds that § 829(f)(1), which refers to "this subchapter" *and* "regulations," is not probative because it was enacted after the original CSA. Opp. 35. That does not matter. Because statutory construction "is a 'holistic endeavor,'" *Koons Buick Pontiac GMC, Inc. v. Nigh*, 543 U.S. 50, 60 (2004), courts apply the contrasting-use canon even when provisions were "enacted separately," *Averett v. U.S. Dep't of Health & Human Servs.*, 306 F. Supp. 3d 1005, 1018 (M.D. Tenn. 2018), so long as they are "related," 2A *Sutherland Statutory Construction* § 46:6 (7th ed. 2020). *E.g.*, *Owensboro Health, Inc. v. U.S. Dep't of Health & Human Servs.*, 832 F.3d 615, 621-22 (6th Cir. 2016).

[2] It is actually the Government that relies on ambiguous snippets of legislative history, along with other weak and obscure authority. Opp. 35-36. Some of these sources are not even on-point; more important, none of them explains how the 2018 amendment would have any effect under the Government's reading.

Anyway, the same inference arises from the *original* CSA. Walmart pointed to § 828(a), which the Government dismisses because it uses the word "subsection," not "subchapter." Opp.35 n.7. That too is irrelevant; the point is Congress referred to part of the statute "*and regulations*," 21 U.S.C. § 828(a) (emphasis added), while § 842(a)(5) refers *only* to the statute. In another "original" CSA provision, Congress spoke of "this subchapter or regulations thereunder." 21 U.S.C. § 880(d)(1). And the Government itself identifies a host of other CSA provisions that refer expressly to "regulations," proving Walmart's point about Congress' usage. Opp. 32-33.

Against all this, the Government insists that *other* CSA provisions use "this subchapter" to include regulations. Opp. 33-34. Not so. Section 843(a)(4)(A) refers to documents "required to be made, kept, or filed under this subchapter," but the Government identifies no authorities that have construed that language to sweep in documents mandated by *regulation*. Both of the cited cases involved falsified *prescriptions*, which the CSA itself requires be "retained," 21 U.S.C. § 829. *United States v. Tull-Abreu*, 921 F.3d 294, 298 (1st Cir. 2019); *United States v. Lartey*, 716 F.2d 955, 957 (2d Cir. 1983). *Lartey* also involved other reports, but the defendant did not dispute they were required "under this subchapter"; he argued only that his conviction was improper since he did not "file" them. 716 F.2d at 964-65. So neither court addressed the statute-versus-regulation issue. Section 843 therefore presents a similar interpretive *question*, but does not advance the Government's *answer*.

Nor does the other cited provision, because it uses materially different terms from those at issue here and in *Kucana*. Section 841 refers to acts "authorized by" this subchapter, 21 U.S.C. § 841(a), not acts "required under" it. Since the CSA empowers the agency to, "by regulation, waive" statutory requirements, *id.* § 822(d), acts authorized by those waivers are, by extension, "authorized by" the CSA. It does not follow that a report mandated by regulation is "required under" the CSA. Indeed, § 841 itself refers to "section 830 of this title, *or the regulations issued under that section*," in discussing "reporting requirements." *Id.* § 841(c)(3) (emphasis added). Again, Congress called out regulatory requirements expressly when it wanted to.

Finally, if any doubt remains, the tie-breaking principle is "the rule of lenity," which "applies" since § 842(a)(5) has "both criminal and noncriminal applications." *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004); *see* 21 U.S.C. § 842(c)(2)(A) (criminal penalties). That canon compels Walmart's construction.

B. Only Orders That Are Actually Identified as Suspicious Must Be Reported.

Count III also fails because it claims that Walmart failed to "detect" suspicious orders, whereas the regulation requires distributors to report suspicious orders only "when discovered," 21 C.F.R. § 1301.74(b).[3]

[3] The Government suggests that a handful of its allegations state claims even under Walmart's reading of the regulation. Opp. 30 n.6. Any such claims fail for the reasons explained in Part III.A.

Textually, the Government says the "when discovered" language requires "*promptness* in reporting." Opp. 29. Even if so, the duty does not kick in unless and until the distributor "discover[s]" the order to be suspicious. That also makes contextual sense, since the reporting duty follows a sentence requiring distributors to "design and operate a system to disclose to the registrant suspicious orders." 21 C.F.R. § 1301.74(b). Once that system flags an order, it must be reported.

The Government objects that this reading would allow distributors to bypass reporting just "by declining to identify" suspicious orders. Opp. 29. That ignores the *independent* regulatory duty to "design and operate" a monitoring system, which DEA can enforce by threat of deregistration. DEA never used that power to contest Walmart's monitoring systems at the time; nor did it ever define an adequate system.

Last, the Government seeks deference to DEA's "reasonable" interpretation, citing two administrative orders. Opp. 29-30. But the regulation is not ambiguous on this point, so no deference is due. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). The administrative orders also came decades after DEA promulgated the regulation, further undercutting deference. *Id.* at 2412. Plus, these were *revocation orders*, so it did not matter whether the distributors had failed at the system-design phase or reporting phase; both are grounds for revocation and DEA had no need to parse them. 21 U.S.C. § 824(a)(4). Here the difference matters, because civil monetary penalties are available only for *reporting* failures. *Detection* failures do not suffice.

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WORD COUNT CERTIFICATION

The undersigned hereby certifies that Defendants' Reply Brief in Support of its Motion to Dismiss contains 3,999 words (exclusive of the cover page, table of contents, table of authorities, and signature block) in Times New Roman 14-point font, counted using Microsoft Word's word count feature.

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